**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF MASSACHUSETTS**

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| IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION | ) | MDL NO. 1456 |
| | ) | CIVIL ACTION: 01-CV-12257-PBS |
| | ) | Judge Patti B. Saris |
| THIS DOCUMENT RELATES TO THE CLASS ACTION | ) | |

**TRACK TWO DEFENDANTS' MOTION TO STRIKE PORTIONS OF THE FOURTH AMENDED MASTER CONSOLIDATED CLASS ACTION COMPLAINT AND NOTICE OF ERRATA**

Over three years ago, the Court admonished plaintiffs that the time for adding new drugs to this massive litigation had passed. (*See* 1/13/2003 Hr'g Tr. at 103.) Nevertheless, with the filing of their *Fourth Amended Master Consolidated Class Action Complaint* ("FAMCC"), plaintiffs are trying to expand dramatically the number of subject drugs for Track 2 Defendants. Not only does the FAMCC covertly add scores of new drugs, it also fails to *precisely identify*, for each proposed class representative, the specific Defendant and specific drugs at issue.

To prevent this case from descending into chaos, corrective action is required. This Court should strike from the FAMCC (and Notice of Errata, including new Exhibit A) both Plaintiffs' newly-added drugs and Plaintiffs' inadequate specification of Defendants and drugs.[1]

**BACKGROUND**

On August 16, 2005, the Court denied in part Plaintiffs' motion for class certification as to the Track 1 Defendants. (Docket No. 1648.) In that decision, the Court determined that association plaintiffs lack standing to assert various claims. (Docket No. 1648 at 4.) Plaintiffs' *Second Amended Master Consolidated Class Action Complaint* ("SAMCC") had

[1] The differences among the prior complaint, the FAMCC, the Notice of Errata, and its attached Exhibit A are highlighted in the attached Exhibit 1. A redlined draft of the FAMCC striking the offending additions is attached as Exhibit 2. A redlined draft of the proposed substitution for page 18 of the Complaint is attached as Exhibit 3. A redline draft of the new Exhibit A to the FAMCC is attached as Exhibit 4.

proposed various classes with associations as representatives, and the ruling left these classes without representatives. The Court granted Plaintiffs a limited opportunity to remedy that deficiency, giving them leave to "amend the SAMCC to propose individual class plaintiffs who are Medicare Part B beneficiaries" as against Track 1 Defendants within 60 days. (*Id.*)

On October 17, 2005 -- roughly 60 days after the Court's Class Certification Order -- Plaintiffs filed their *Third Amended Master Consolidated Class Action Complaint* ("TAMCC"). That pleading attempted to correct the identified deficiencies of the SAMCC by proposing new Plaintiffs to represent classes as against Track 1 Defendants. Although the TAMCC also included other changes, the changes relating to the Track 1 Defendants were relatively minor.

On November 21, 2005, the Court entered Case Management Order No. 16 ("CMO 16"), which extended Plaintiffs the same opportunity to identify individual class representatives as against the Track 2 Defendants. (Docket No. 1897.) To that end, the Court permitted Plaintiffs to amend the SAMCC "to add plaintiffs or proposed class representatives for claims against Track Two Defendants . . . within 30 days of this Court's final order regarding class certification with respect to the Track One Defendants." (CMO 16 at ¶ 1.) The Court made clear that "[a]ny amendment to add proposed class representatives *shall allege facts demonstrating the typicality and adequacy of the new proposed class representatives*." (*Id.* (emphasis added).) In a prior order, the Court had explained that precision in such pleading is crucial; at a minimum, proper allegations should include "with respect to each defendant: (1) the specific drug or drugs that were purchased from defendant, (2) the allegedly fraudulent AWP for each drug, and (3) the name of the specific plaintiff(s) that purchased the drug." (Docket No. 361 at 45.)

On January 30, 2006, the Court entered its Consolidated Order re: Motion for Class Certification as to Track 1 Defendants, triggering Plaintiffs' 30 days to amend the SAMCC to add plaintiffs or proposed class representatives with respect to Track 2 Defendants. (Docket No.

2097.) On March 1, 2006, 30 days after the Court's final order regarding class certification, Plaintiffs filed the FAMCC. In so doing, Plaintiffs flagrantly abused the limited opportunity for correction afforded them by this Court.

*First*, Plaintiffs went well beyond simply adding new proposed class representatives, interspersing literally scores of new drugs complained of throughout the individual class representative allegations. (*See generally* FAMCC § III.A.) Plaintiffs never sought, and this Court never granted, leave to add these expansive new allegations; indeed, the Court had already made clear that the universe of drugs at issue in this case was closed. (1/13/2003 Hr'g Tr. at 103 (responding to Plaintiffs' suggestion that they merely re-plead to add additional drugs, the Court stated: "I gave [Plaintiffs] the chance for this megacomplaint . . . we've got to move this forward if it's going to get past this hurdle.").)

Plaintiffs were not forthright about their addition of new drugs to the FAMCC. The FAMCC simply added the new drugs by sprinkling them throughout the new proposed class representative allegations. Also, the copy of the FAMCC served on Defendants, as with prior complaints, referenced an Exhibit A and Exhibit B as listing the relevant drugs -- but it did not include any such exhibits. Then, on March 10, 2006, Plaintiffs served a "Notice of Errata" -- which purported to fix various technical defects in the FAMCC, and also added the missing Exhibits A and B. Yet, this new Exhibit A -- which is vastly expanded from the version appended to the TAMCC -- goes well beyond even the FAMCC, adding yet more drugs. (*See* Ex. 1.)

*Second*, Plaintiffs failed to comply with this Court's clear directive to be precise. (Docket No. 361 at 45.) Plaintiffs added purported class representatives and named each not only as against *specified* Defendants, but also as to other *unspecified* Defendants. (*E.g.*, FAMCC ¶ 15 (Plaintiff Susan Aaronson "is a proposed class representative for" certain defendants,

"*among other defendants*") (emphasis added); *id.* ¶¶ 17-24 (same for other Plaintiffs).) In addition, Plaintiffs refused to specify the drugs applicable to each named Defendant. These examples are illustrative:

- FAMCC ¶ 29: "Because [Plaintiff and proposed class representative Pirelli Armstrong Tire Corporation Retiree Medical Benefits Trust] is composed of retirees, about two-thirds of whom are eligible for Medicare, and because the search was only of a relatively small number of files, plaintiffs are confident that further investigation will show that other drugs were paid for in the Medicare Part B context with respect to the various companies known in this case as 'Track 1' and 'Track 2' Defendants. Our investigation is continuing."

- *Id.* ¶ 30: Specifying, for Plaintiff and proposed class representative Sheet Metal Workers National Health Fund, only Track 2 Defendants but not any specific Track 2 drugs paid for by them.

- *Id.* ¶ 39: For Plaintiff and proposed class representative Pipefitters' Local Union 357, setting out no Defendants and as to drugs merely stating: "All of Pipefitters drugs that are at issue in the Complaint are identified in Exhibit A."

- Notice of Errata ¶ 39a: For Plaintiff and proposed class representative Health Care For All, stating only that "HCFA's members have been billed for and paid charges for [unspecified drugs] outside of the Medicare Part B context . . . ."

## ARGUMENT

In its August 16, 2005 opinion and in CMO 16, this Court afforded Plaintiffs an opportunity to remedy their pleading missteps concerning class representatives. (*See* Docket No. 1648; Docket No. 1897.) But the Court did not open the door to the expansion of this litigation through the inclusion of additional subject drugs. Neither did the Court grant leave to name proposed class representatives who could not identify the specific Defendants against whom they sought to bring claims. Such unabashed violation of the Federal Rules of Civil Procedure and this Court's orders should not permitted. The offending new material in the FAMCC and Notice of Errata (as well as the new Exhibit A) should be stricken.

## I. ALLEGATIONS CONCERNING NEW DRUGS, NOT PREVIOUSLY PLEADED, SHOULD BE STRICKEN.

Most egregiously, Plaintiffs have tried in the FAMCC to add dozens of new drugs in this case. This is improper -- especially given that the Court had already ruled that the universe of drugs at issue in this case was closed. (1/13/2003 Hr'g Tr. at 103.) Instead of unilaterally deciding to transform and expand this already behemoth case, plaintiffs should at least have sought leave to amend. They did not, and these allegations of the FAMCC can be stricken on that basis alone. *See* Fed. R. Civ. P. 15(a) ("a party may amend the party's pleading only by leave of court"). Nor is it any answer that the Court allowed *some* leave to amend. It did not grant them leave to add these drugs, and Plaintiffs were not free to expand the scope of the leave. *See* Fed. R. Civ. P. 15(a); *McNell v. Hugel*, 1995 U.S. Dist. LEXIS 4681, *6 (D.N.H. Mar. 31, 1995) (dismissing counts of amended complaint that exceeded the parameters of the court's permission to amend).

In any event, if Plaintiffs (1) had not ignored this Court's orders (which they did) and (2) sought leave to add these new drugs (which they did not), their request to do so should have failed just the same. The "amendment policy prescribed by Rule 15(a) does not mean that leave will be granted in all cases." *Acosta-Mestre v. Hilton Int'l of Puerto Rico, Inc.*, 156 F.3d 49, 51 (1st Cir. 1998) (quoting 6 Charles Alan Wright et al., *Federal Practice and Procedure* § 1487 at 611 (2d ed. 1990)). More specifically, (1) undue delay in filing a motion to amend and (2) undue prejudice to the opposing party by virtue of allowance of the amendment are both sufficient reasons to deny a request to amend a plaintiff's complaint. *Id.* Plaintiffs' attempt to add dozens of new drugs to this case nearly 4 years into this litigation -- and after discovery deadlines have been extended several times -- falls squarely within both of these descriptions.

*First*, when "considerable time has elapsed between the filing of the complaint and the motion to amend, the movant has the burden of showing some 'valid reason for his neglect and delay.'" *Acosta-Mestre*, 156 F.3d at 52. Indeed, "the First Circuit has more than once recognized" that denial of leave to amend is appropriate where, as here, "there was an 'undue delay' in filing the motion to amend." *McSorley v. Richmond*, 2002 WL 31106427, *1 (D. Me. Sept. 20, 2002). Here, litigation has been ongoing in this Court for nearly 4 years. Yet only now have Plaintiffs added this host of new drugs. And not only have they not offered any "valid reason for [their] neglect and delay," Plaintiffs apparently hoped quietly to slip these drugs into the FAMCC and Notice of Errata (including the new Exhibit A), undetected. This will not do. Such "undue delay" in seeking amendment, without any valid explanation, may be a sufficient basis *by itself* for denying leave to amend. *See, e.g.*, *Acosta-Mestre*, 156 F.3d at 52 (affirming denial of leave after fifteen-month delay); *Grant v. News Group Boston, Inc.*, 55 F.3d 1, 5 (1st Cir. 1995) (affirming denial of leave after fourteen-month delay); *Stepanischen v. Merchants Despatch Transp. Corp*., 722 F.2d 922, 933 (1st Cir. 1983) (affirming denial of motion for leave filed after seventeen-month delay); *Hayes v. New England Millwork Distribs., Inc*., 602 F.2d 15, 19 (1st Cir. 1979) ("[I]t is clear that 'undue delay' can be a basis for denial.").

*Second*, permitting the new drug allegations at this late stage of the litigation would unquestionably cause Defendants undue prejudice. Defendants have already spent thousands of hours taking (not to mention producing) discovery based on the numerous drugs Plaintiffs identified previously. If the Court allows the new drug allegations, Defendants would have to go back to all of the parties from which they sought discovery and seek additional discovery relating to the new drugs. In addition, the parties' Rule 26 obligations could require them to needlessly search and produce documents relating to the new drugs -- wasting hundreds of thousands of dollars and countless hours to redo what has already been done. Worse, the entire litigation

would need to be stalled -- once again -- to afford the parties adequate time for Defendants to complete offensive and defensive discovery. Thus, even if Plaintiffs had presented the Court with supposedly valid reasons for their extended delay (and they did not), the undue prejudice Defendants would suffer necessitates striking Plaintiffs' new drug allegations. *See, e.g.*, *Quaker State Oil Refining Corp. v. Garrity Oil Co. Inc.*, 884 F.2d 1510, 1517-18 (1st Cir. 1989) (motion for leave to amend denied based on undue prejudice where a great deal of discovery had already taken place).[2]

Thus, Plaintiffs' new drug allegations should be stricken. It follows that, if all drugs for a given Defendant are stricken for a proposed representative, that representative should be stricken as to that Defendant. (*See* Exs. 2 & 3.)

## II. ALLEGATIONS WHICH DO NOT TIE PROPOSED CLASS REPRESENTATIVES TO SPECIFIC DEFENDANTS AND DRUGS SHOULD BE STRICKEN.

Even as to what this Court's orders permitted them to do, add new proposed class representatives, Plaintiffs refused to follow this Court's plain instruction to be specific. (Docket No. 361 at 45.) By asserting that new proposed class representatives should head classes both against *specified* Defendants and other *unspecified* Defendants, the FAMCC plainly violates the Court's instruction to "clearly and concisely allege with respect to *each Defendant*." (*E.g.*, FAMCC ¶ 15 (Plaintiff Susan Aaronson "is a proposed class representative for" certain defendants, "*among other defendants*") (emphasis added; *id.* ¶¶ 17-24 (same).) Nor is this a mere technicality: Plaintiffs seem content to list only some Defendants in pleading each

[2] There may even be a third reason to deny amendment -- the well-known rule that amendment should be denied if it would be futile. *Correa-Martinez v. Arrillaga-Belendez*, 903 F.2d 49, 59 (1st Cir. 1990) ("Where an amendment would be futile or would serve no legitimate purpose, the district court should not needlessly prolong matters."). Here, Plaintiffs' new drug amendments go to their state law consumer fraud claims. The statutes of limitations have long since run on such claims; it would be futile to allow amendment to raise such claims as to new drugs for the first time. *See, e.g.*, *Harvey v. Snow*, 281 F.Supp.2d 376, 381-82 (D.R.I. 2003.) (denying leave to amend as futile because the statute of limitations had run on the proposed new claim).

proposed representative's claims, but then slipping in others elsewhere (much later) in the FAMCC. (*Compare, e.g.*, FAMCC ¶ 18 (Robert Howe is a class representative against Amgen, AstraZeneca, Aventis, GSK, Sircor [sic] and Watson, "among other defendants"), *with id.* ¶ 590 (Robert Howe is a class representative against "Abbott, Amgen, Aventis, Baxter, Fujisawa, Immunex, Sicor and Watson").) This will not do; the "among other defendants" language in each of these counts should be stricken.

Plaintiffs also refused to specify the drugs tying each proposed representative to each named Defendant. Sometimes, Plaintiffs alleged Track 2 Defendants but no specific drugs. (*E.g.*, FAMCC ¶ 30.) Other times, Plaintiffs alleged neither specific drugs nor Defendants. (*E.g.*, *id.* ¶ 29) (as to Plaintiff and proposed class representative Pirelli Armstrong Tire Corporation Retiree Medical Benefits Trust, "plaintiffs are confident that further investigation will show that other drugs were paid for in the Medicare Part B context with respect to the various companies known in this case as 'Track 1' and 'Track 2' Defendants. Our investigation is continuing."); *id.* ¶ 39 (as to plaintiff and proposed class representative Pipefitters' Local Union 357, setting out no Defendants and failing to specify the drugs: "All of Pipefitters drugs that are at issue in the Complaint are identified in Exhibit A."); Notice of Errata ¶ 39a: For Plaintiff and proposed class representative Health Care For All, stating only that "HCFA's members have been billed for and paid charges for [unspecified drugs] outside of the Medicare Part B context . . . .".)

Clearly, this falls well short of the notice this Court's Orders -- and indeed, the law -- contemplate. (Docket No. 361 at 45 (explaining that proper allegations should include, "with respect to each defendant: (1) the specific drug or drugs that were purchased from defendant, . . . and (3) the name of the specific plaintiff(s) that purchased the drug.")); *see Valley Forge Christian College v. Americans United for Separation of Church & State, Inc.*, 454 U.S. 464, 472

(1982) (noting that plaintiff bears the burden of demonstrating standing and must plead its components with specificity); *James v. City of Dallas*, 254 F.3d 551, 563 (5th Cir. 2001) (explaining that "[b]oth standing and class certification must be addressed on a claim-by-claim basis," and "at least one named Plaintiff must have standing" with respect to "each of the claims") (collecting cases); *Prado-Steiman ex rel. Prado v. Bush*, 221 F.3d 1266, 1280 (11th Cir. 2000) ("It is not enough that a named plaintiff can establish a case or controversy between himself and the defendant by virtue of having standing as to one of many claims he wishes to assert. Rather, each claim must be analyzed separately, and a claim cannot be asserted on behalf of a class unless at least one named plaintiff has suffered the injury that gives rise to that claim.") (internal quotation marks omitted). These additions to Plaintiffs' FAMCC should, therefore, be stricken.

## CONCLUSION

Plaintiffs should not be permitted to abuse this Court's limited grant of leave to fix their pleadings as to class representatives by taking this case back to square one. For the foregoing reasons, this Court should strike from the FAMCC (and Notice of Errata, including new Exhibit A) both Plaintiffs' newly-added drugs and Plaintiffs' inadequate specification of Defendants and drugs -- as set forth in Exhibits 2 and 3.

Dated: March 13, 2006

Respectfully submitted,

ON BEHALF OF THE TRACK 2 DEFENDANTS,

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**CERTIFICATION PURSUANT TO LOCAL RULE 7.1**

I certify that the moving parties have communicated with counsel for Plaintiffs in an effort to resolve the dispute referred to in this motion, and that the parties have not been able to reach agreement with respect thereto.

/s/ Toni-Ann Citera
Toni-Ann Citera

**CERTIFICATE OF SERVICE**

I, Toni-Ann Citera, hereby certify that I am one of Abbott Laboratories' attorneys, and that I caused a true and correct copy of the foregoing TRACK TWO DEFENDANTS' MOTION TO STRIKE PORTIONS OF THE FOURTH AMENDED MASTER CONSOLIDATED CLASS ACTION COMPLAINT AND PROPOSED CONSOLIDATED ORDERS (VERSIONS 1 AND 2) RE: MOTION FOR CLASS CERTIFICATION TRACK 2 to be served on all counsel of record electronically by causing same to be posted via LexisNexis, this 14th day of March, 2006.

/s/ Toni-Ann Citera
Toni-Ann Citera